K050595

MAY 2 3 2005

510(k) Summary of Safety and Effectiveness in accordance with 21 CFR 807.92

(a) (1) **Submitted by:**

Midwest Development
1200 South York Road, #4180
Elmhurst, Illinois 60126

Tel.: 630.758.0470
Fax: 630.758.0471
E-mail: stan@drkovaklaser.com

Contact Person: Dr. Stanley Kovak, M.D.

Position/Title: President

Date of Preparation: May 20, 2005

(2) **Trade Name:** **FT2000** Sequencer for Muscle Stimulator
CI2000 PC Software

Common/Classification Name: POWERED MUSCLE STIMULATOR

Product Code: IPF, 21 CFR § 890.5850

Class: Class II

(3) **Predicate Device(s):**

K972244 NT2000, Bio-Medical Research, Ltd.

Reason for Submission: New Device

(4) **Description of Device:**

A sequenced system for transcutaneous muscle stimulation consists of a stimulator, a sequencer for programmable timed channel selection, patient cable, and electrodes applied to the skin.

Various types of time-variable waveforms may be output to generate the desired effect on the muscle(s) to be treated, and the patient is given control of the signal intensity for personal safety and comfort. Sequenced systems may have more than one output channel in order to operate bilaterally on the body or to treat multiple regions simultaneously or serially in a prescribed sequence.

K050595

The **FT2000** is a sequencing device only – it does not generate stimulation signals, but directs the signals from the stimulator to the patient, applying a physician prescribed sequence to the treatment. Sequenced treatment has several advantages, including patient convenience and controlled treatment of specific sites.

The **FT2000** Sequencer is designed to mechanically and electrically mate with the NT2000, manufactured by Bio-Medical Research, Ltd., a 510(k) listed device which provides muscle stimulation signals.

(5) **Intended use:**

Medical devices providing transcutaneous muscle stimulation have been available for many years. Indications have included muscle reeducation and toning, increasing local blood flow, and maintaining muscle range of motion.

Indications for Use:

When used in combination with a listed stimulator, such as the NT2000 manufactured by Bio-Medical Research Ltd., the Midwest Development **FT2000** Sequencer provides electrical neuromuscular stimulation for the purposes of relaxation of muscle spasm, prevention or retardation of disuse muscle atrophy, muscle re-education, increase local blood circulation, or to maintain or increase range of motion.

Sequencing provided by the **FT2000** directs the stimulator signal from the stimulator device to selected patient electrode sites without modifying the original signal characteristics.

The **FT2000** permits treatment in user selected time sequences of up to 24 pairs of electrodes by having 12 pairs on each side of the body. The **CI2000** Software allows the user to set treatment times for each electrode pair.

The **FT2000** is a prescription device.

(6) **Technological Characteristics:**

The **FT2000** embodies similar technological characteristics as the predicate devices. Both devices employ embedded microcontrollers to store and provide treatment profiles to the user. Both have a means for the patient to easily control or suspend treatment. Both devices are battery operated to ensure that treatment is isolated.

K050595

As stated in (4), the **FT2000** is a sequencing device only – it does not generate stimulation signals, but directs the signals from the stimulator to the patient via a bank of relays per a prescribed treatment profile.

The **CI2000** PC software allows the physician to set up a treatment profile for the patient and store it in the **FT2000**. Treatment profiles cannot be modified by the patient.

(b) (1) **Non-Clinical Tests Submitted:**

The **FT2000** has been tested in accordance with applicable standards for medical device electrical safety, electromagnetic compatibility, and particular requirements for safety of nerve and muscle stimulators. The **FT2000** passed all of the tests.

Accessories also meet safety requirements: 510(k) listed electrodes are specified, and the patient cable utilizes shrouded connectors to meet lead wire safety requirements.

System level testing including waveform testing was performed in combination with the NT2000 stimulator.

FT2000 embedded software and **CI2000** PC software was verified to requirements and validated to meet intended use. Risk analysis and failure analysis were performed – residual risks were determined to be acceptable.

(2) **Clinical Tests Submitted:** (None)

(3) **Conclusions from Tests:**

As described in (b)(1) above, all of the testing demonstrates that the Midwest Development **FT2000** with **CI2000** PC software is as safe and effective as, and functions in a manner equivalent to the predicate devices: the NT2000 (Bio-Medical Research, Ltd.).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 3 2005

Midwest Development
C/o Mr. Stephen Gorski
Imagenix, Inc.
S65 W35739 Piper Road
Eagle, Wisconsin 53119

Re: K050595
Trade/Device Name: FT2000 Sequencer for Muscle Stimulator
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: II
Product Code: IPF
Dated: February 28, 2005
Received: March 8, 2005

Dear Mr. Gorski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Miriam C. Provost

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K050595**

Device Name: Midwest Development FT2000 Sequencer for Muscle Stimulator

Indications for use:

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Sequencing provided by the FT2000 directs the stimulator signal from the stimulator device to selected patient electrode sites without modifying the original signal characteristics.

The FT2000 permits treatment in user selected time sequences of up to 24 pairs of electrodes by having 12 pairs on each side of the body. The CI2000 Software allows the user to set treatment times for each electrode pair.

Contraindications for use:

Electrical neuromuscular stimulation is contraindicated in patients with implanted biomedical electronic devices such as cardiac demand pacemakers.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Prescription Use ___X___ AND / OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K050595